U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE

HEARING CHARTER

Environmental and Safety Impacts of Nanotechnology: What Research is Needed?

Thursday, November 17, 2005
10:00 a.m. - Noon
2318 Rayburn House Office Building

1. Purpose

On Thursday, November 17, 2005, the Committee on Science of the House of Representatives will hold a hearing to examine current concerns about environmental and safety impacts of nanotechnology and the status and adequacy of related research programs and plans. The federal government, industry and environmental groups all agree that relatively little is understood about the environmental and safety implications of nanotechnology and that greater knowledge is needed to enable a nanotechnology industry to develop and to protect the public. The hearing is designed to assess the current state of knowledge of, and the current research plans on the environmental and safety implications of nanotechnology.

2. Witnesses

Dr. Clayton Teague is the Director of the National Nanotechnology Coordination Office, the office that coordinates Federal nanotechnology programs. The office is the staff arm of the Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council (NSTC). NSTC includes all federal research and development (R&D) agencies and is the primary coordination group for federal R&D policy.

Mr. Matthew M. Nordan is the Vice President of Research at Lux Research Inc., a nanotechnology research and advisory firm.

Dr. Krishna C. Doraiswamy is the Research Planning Manager at DuPont Central Research and Development, and is responsible for coordinating DuPont's nanotechnology efforts across the company's business units.

Mr. David Rejeski is the Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars.

Dr. Richard Denison is a Senior Scientist at Environmental Defense.

3. Overarching Questions

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?

- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?

- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

4. Brief Overview

- Nanotechnology is expected to become a major engine of economic growth in the coming years. According to Lux Research,[1] a private research firm that focuses on nanotechnology, in 2014 there could be $2.6 trillion worth of products in the global marketplace which have incorporated nanotechnology —15 percent of manufacturing output. Lux also predicts that in 2014, 10 million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.

- There is a growing concern in industry that the projected economic growth of nanotechnology could be undermined by real environmental and safety risks of nanotechnology or the public's perception that such risks exist.

- The small size, large surface area and unique behavioral characteristics of nanoparticles present distinctive challenges for those trying to assess whether these particles pose potential environmental risks. For example, nanoscale materials such as buckyballs, nano-sized clusters of carbon atoms, behave very differently than their chemically-equivalent cousin, pencil lead. There is an unusual level of agreement among researchers, and business and environmental organizations that basic scientific information needed to assess and protect against potential risks does not yet exist.

- In December 2003, the President signed the *21st Century National Nanotechnology Research and Development Act* (P.L. 108-153), which originated in the Science Committee. This Act provided a statutory framework for the interagency National Nanotechnology Initiative (NNI). Among other activities, the Act called for the NNI to ensure that research on environmental concerns is integrated with broader federal nanotechnology research and development (R&D) activities.

[1] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.

- Federal funding for the NNI has grown from $464 million in fiscal year 2001 (FY01) to a requested $1.1 billion in FY06. Of the requested FY06 level, the President's budget proposes that $38.5 million (4 percent of the overall program) be directed to research on environmental and safety implications of nanotechnology.

5. Background

The National Academy of Sciences describes nanotechnology as the "ability to manipulate and characterize matter at the level of single atoms and small groups of atoms." An Academy report describes how "small numbers of atoms or molecules ... often have properties (such as strength, electrical resistivity, electrical conductivity, and optical absorption) that are significantly different from the properties of the same matter at either the single-molecule scale or the bulk scale." [2]

Nanotechnology is an enabling technology that will lead to "materials and systems with dramatic new properties relevant to virtually every sector of the economy, such as medicine, telecommunications, and computers, and to areas of national interest such as homeland security."[3] As an enabling technology, it is expected to be incorporated into existing products, resulting in new and improved versions of these products. Some nanotechnology-enabled products are already on the market, including stain-resistant, wrinkle-free pants, ultraviolet-light blocking sunscreens, and scratch-free coatings for eyeglasses and windows. In the longer run, nanotechnology may produce revolutionary advances in a variety of industries, such as faster computers, lighter and stronger materials for aircraft, more effective and less invasive ways to find and treat cancer, and more efficient ways to store and transport electricity.

The projected economic growth of nanotechnology is staggering. In October 2004, Lux Research, a private research firm, released its most recent evaluation of the potential impact of nanotechnology. The analysis found that, in 2004, $13 billion worth of products in the global marketplace incorporated nanotechnology. The report projected that, by 2014, this figure will rise to $2.6 trillion—15 percent of manufacturing output in that year. The report also predicts that in 2014, ten million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.[4]

6. How Might Environmental and Safety Risks Affect the Commercialization of Nanotechnology?

Lux Research Report on Environmental and Safety Risks of Nanotechnology

In May, 2005, Lux Research published a comprehensive analysis of how environmental and safety risks could affect the commercialization of nanotechnology.[5] While a limited number of studies have been done on specific environmental impacts, the report concludes that the few that

[2] *Small Wonders, Endless Frontiers: A Review of the National Nanotechnology Initiative*, National Research Council/National Academy of Sciences, 2002.
[3] Id.
[4] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.
[5] Lux Research, "A Prudent Approach to Nanotech Environmental, Health and Safety Risks." May 2005

have been done raise sufficient cause for concern. This leads to what the report calls a fundamental paradox facing companies developing nanotechnology: "They must plan for risks without knowing precisely what they are." The report then identifies two classes of risk that are expected to effect commercialization: "*real* risks that nanoparticles may be hazardous and *perceptual* risks that they pose a threat regardless of whether or not it is real." The report calculates that at least 25 percent of the $8 trillion in total projected revenue from products incorporating nanotechnology between 2004 and 2014 could be affected by real risks and 38 percent could be affected by perceived risk."

The report describes that varying levels of risk are suspected for different types of nanomaterials and products and for different phases of a product's life cycle. For example, some nanoclay particles raise little initial concern because they would be locked up in composites to be used in automotive bodies. On the other hand, cadmium-selenide quantum dots that could be injected into the body for medical imaging tests are highly worrisome due to the toxicity of cadmium-selenide and the fact that they would be used within the human body.

Another factor that contributes to the potential risk of different nanotechnology-related products is the expected exposure of people and the environment over the product's life cycle. The manufacturing phase is the first area of concern because workers potentially face repeated exposure to large amounts of nanomaterials.[6] During product use, the actual risk will vary depending in part on whether the nanoparticles have been fixed permanently in a product, like within a memory chip in a computer, or are more bioavailable, like in a sunscreen where exposure may be more direct or may continue over a long period of time. Finally, the greatest uncertainties exist about the risks associated with the end of a product's life because it is difficult to predict what method of disposal, such as incineration or land disposal, will be used for a given material, and there has been little research on, for example, what will happen to nanomaterials within products stored in a landfill over 100 years.

The Lux Research report finds that nanotechnology also faces significant perceived risks. These risks are driven by people's general concerns about new technologies that they may be exposed to without being aware of it. However, public perceptions of nanotechnology are still up in the air and may be influenced by the press and non-governmental organizations. The report argues that, with a concerted effort to emphasize the benefits of nanotechnology, communicate honest assessments of toxicological effects, and engage all interested stakeholders from the outset, the public could be made comfortable with this new technology.

Woodrow Wilson International Center Study on Public Perceptions

A more in-depth survey of public perception of nanotechnology was recently completed by Woodrow Wilson Center's Project on Emerging Technologies.[7] The study found that the public

[6] Lux Research's findings on worker exposure are consistent with the concerns expressed in the recent report on the NNI by the President's Council of Advisors on Science and Technology. The report, *National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel*, is available online at http://www.nano.gov/FINAL_PCAST_NANO_REPORT.pdf.

[7] *Informed Public Perception of Nanotechnology and Trust in Government*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars is available online at http://www.pewtrusts.com/pdf/Nanotech_0905.pdf.

currently has little knowledge about nanotechnology or about how risks from nanotechnology will be managed. This lack of information can lead to mistrust and suspicion. However, the study shows that when people learned more about nanotechnology and its promised benefits, approximately 80 percent were supportive or neutral about it. Once informed, people also expressed a strong preference for having more information made available to the public, having more testing done before products were introduced, and having an effective regulatory system. They do not trust voluntary approaches and tend to be suspicious of industry. The lesson, according to the report, is that there is still time to shape public perception and to ensure that nanotechnology is developed in a way that provides the public with information it wants and establishes a reasonable regulatory framework.

7. Emerging Environmental and Safety Concerns

Initial research on the environmental impacts of nanotechnology has raised concerns. For example, early research on buckyballs (nano-sized clusters of 60 carbon atoms) suggests that they may accumulate in fish tissue. Although it may turn out that many, if not most, nanomaterials will be proven safe in and of themselves and within a wide variety of products, more research is needed before scientists can determine how they will interact with people and the environment in a variety of situations.

Nanotechnology's potential to affect many industries stem from that fact that many nanoscale materials behave differently than their macroscale counterparts. For example, nano-sized quantities of some electrical insulating materials become conductive, insoluble substances may become soluble, some metals become explosive, and materials may change color or become transparent. These novel features create tremendous opportunities for new and exciting applications, but also enable potentially troubling new ways for known materials to interact with the human body or be transported through the environment. It is difficult and would be misleading to extrapolate from current scientific knowledge on how materials behave in their macro-form to how they will behave in nano-form, and new techniques to assess toxicity, exposure, and ultimately public and environmental risks from these materials may be needed.

Widely Recognized Research and Development Needs

Businesses, non-governmental organizations, academic researchers, federal agencies, and voluntary standards organizations all have efforts underway to address concerns about the environmental and safety implications of nanotechnology. However, a number of organizations, including business associations and environmental groups, worry that environmental R&D is not keeping pace with the rapid commercialization and development of new nanotechnology-related products. There is widespread agreement on the following research and standards needs:

- Nanotechnology needs an accepted nomenclature. For example, "buckyballs" is the equivalent of a trade name; it does not convey critical information about the content, structure, or behavior of nanoparticles as traditional chemical nomenclature does for traditional chemicals. The lack of nomenclature creates a variety of problems. For example, it is difficult for researchers to know whether the nanomaterial they are working with is the same as that presented in other research papers. Similarly, it is difficult for a company to

know whether it is buying the same nanomaterial from one company that it previously bought from another.

- Nanotechnology needs an agreed upon method for characterizing particles. Nanoparticles unique size enables unusual behavior. At these small sizes, particles can have different optical and electrical properties than larger particles of the same material. In addition, the large surface area of nanoparticles relative to their mass makes nanoparticles more reactive with their surroundings. Further complicating efforts to characterize nanomaterials is that small changes to some nanoparticles, such as altering the coatings of buckyballs, significantly modify the physical properties (and hence the potential toxicity) of the particles.

- A great deal more information is needed on the mechanisms of nanoparticle toxicity. Early studies suggest that a variety of nanoparticles damage cells through oxidative stress. (Oxidation is believed to be a common source of many diseases such as cancer.) A better understanding of the chemical reactions that nanoparticles provoke or take part in within living organisms will enable researchers to more effectively predict which nanomaterials are most likely to cause problems.

- Basic information on how nanomaterials enter and move through the human body are needed. Early studies point to wide variations in the toxicity of nanomaterials depending on the how exposure occurred – through the mouth, skin contact, inhalation, or intravenously. Particles in the range of 1-100 nanometers are small enough to pass through cell walls and through the blood-brain barrier, making them particularly mobile once they enter the body. There is also concern that some nanoparticles could lodge in the lungs and might be so small as to be overlooked by the body's defense mechanisms that would normally remove these invaders from the body.

- More research is needed on how and why some nanoparticles appear to behave one way as individual particles, but behave differently when they accumulate or agglomerate. One study of buckyballs, for example, found that while individual buckyballs are relatively insoluble, they have a tendency to aggregate, which makes them highly soluble and reactive with bacteria, raising concerns about their transport in watersheds and their impact on ecosystems.

According to a variety of experts, many of whom are familiar with the development of the largely mature databases available on the behavior and toxicity of various chemicals, development of a parallel collection of information on nanotechnology-related materials may take as long as 10-15 years.

Call for a Governmental Program on Environmental and Safety Implications of Nanotechnology

Recently, the American Chemistry Council and the environmental organization, Environmental Defense, agreed on a Joint Statement of Principles that should guide a governmental program for addressing the potential risks of nanoscale materials.[8] They call for, among other things,

[8] Environmental Defense and American Chemistry Council Nanotechnology Panel, Joint Statement of Principles, Comments on EPA's Notice of Public Meeting on Nanoscale Materials, June 23, 2005. The full statement is available online at http://www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf.

- "a significant increase in government investment in research on the health and environmental implications of nanotechnology,"
- "the timely and responsible development of regulation of nanomaterials in an open and transparent process,"
- "an international effort to standardize test protocols, hazard and exposure assessment approaches and nomenclature and terminology,"
- "appropriate protective measures while more is learned about potential human health or environmental hazards," and
- a government assessment of "the appropriateness of or need for modification of existing regulatory frameworks."

8. Federal Government Activities

The National Nanotechnology Initiative (NNI) is a multi-agency research and development (R&D) program begun in 2001 and formally authorized by Congress in 2003.[9] Currently, 11 federal agencies have ongoing programs in nanotechnology R&D, while another 11 agencies participate in the coordination and planning work associated with the NNI. The primary goals of the NNI are to foster the development of nanotechnology and coordinate federal R&D activities.[10]

Federal funding for the NNI has grown from $464 million in FY01 to a requested $1.1 billion in FY06. Of the requested FY06 level, the President's budget proposes that $38.5 million (4 percent of the overall program) be directed to research on environmental, health, and safety implications of nanotechnology (see Table 1).[11]

[9] In 2003, the Science Committee wrote and held hearings on the *21st Century National Nanotechnology Research and Development Act*, which was signed into law on December 3, 2003. The Act authorizes $3.7 billion over four years (FY05 to FY08) for five agencies (the National Science Foundation, the Department of Energy, the National Institute of Standards and Technology, the National Aeronautics and Space Administration, and the Environmental Protection Agency). The Act also: adds oversight mechanisms—an interagency committee, annual reports to congress, an advisory committee, and external reviews—to provide for planning, management, and coordination of the program; encourages partnerships between academia and industry; encourages expanded nanotechnology research and education and training programs; and emphasizes the importance of research into societal concerns related to nanotechnology to understand the impact of new products on health and the environment.

[10] The goals of the NNI are to maintain a world-class research and development program; to facilitate technology transfer; to develop educational resources, a skilled workforce, and the infrastructure and tools to support the advancement of nanotechnology; and to support responsible development of nanotechnology.

[11] There is of course additional federal funding being spent on fundamental nanotechnology R&D that has the potential to inform future studies on environmental and safety impacts, so the $38.5 million may be a low estimate of the relevant research underway.

Table 1. NNI Proposed FY2006 Investments in environmental implications ($ in millions)

Agency	Total Spending on Nanotechnology R&D	Environment, Health and Safety Implications R&D	Percent of Total Environment, Health and Safety Implications R&D
NSF	$344	$24.0	62.3
DOD	$230	$1.0	2.6
DOE	$207	$0.5	1.3
NASA	$32	$0.0	0.0
NIH	$144	$3.0	7.8
NIOSH	$3	$3.1	8.1
DOC	$75	$0.9	2.3
USDA	$11	$0.5	1.3
EPA	$5	$4.0	10.4
DOJ	$2	$1.5	3.9
DHS	$1	$0.0	0.0
Total	**$1054**	**$38.5**	**100.0%**

Source: NNI FY 06 Supplement Report: p. 36, 38.

To coordinate environmental and safety research on nanotechnology, the National Science and Technology Council organized in October 2003 the interagency Nanotechnology Environmental and Health Implications Working Group (NEHI WG), composed of agencies that support nanotechnology research as well as those with responsibilities for regulating nanotechnology-based products. NEHI WG is in the process of developing a framework for environmental R&D for nanotechnology that it expects to release in January 2006. To provide useful guidance to agencies, Congress, academic researchers, industry, environmental groups, and the public, the research framework will need to define the scale and scope of the needed research, set priorities for research areas, provide information that can affect agency-directed spending decisions, and be specific enough to serve as overall research strategy for federal and non-federal research efforts.

Currently, over 60 percent of the environmental research funding is provided by the National Science Foundation (NSF). In FY05 and FY06, NSF is putting a small amount of funding (approximately $1 million each year) into a joint solicitation on investigating environmental and human health effects of manufactured nanomaterials with the Environmental Protection Agency, the National Institute for Occupational Safety and Health (NIOSH), and National Institute of Environmental Health Sciences (NIEHS). However, the majority of the NSF's funding in this area is distributed to projects proposed in response to general calls for nanotechnology-related research; projects are selected based on the quality and potential impact of the proposed research. It is not distributed based on the research needs of regulatory agencies such as EPA, OSHA or FDA. Currently NSF and the research community base their understanding of priorities in environmental research on a 2003 workshop "Nanotechnology Grand Challenge in the

Environment,"[12] but the federal framework being developed by the NEHI WG should provide helpful, updated guidance for future research solicitations and proposals.

EPA's Office of Research and Development is the second largest sponsor of research on the environmental implications of nanotechnology, providing approximately 10 percent ($4 million) of the federal investment. At the beginning of the NNI, EPA focused its research program on the development of innovative applications of nanotechnology designed to improve the environment, but in FY03, EPA began to shift its focus to research on the environmental implications of nanotechnology. In FY04 and FY05, EPA has increasingly tailored its competitive solicitations to attract research proposals in areas that will inform decisions to be made by the agency's regulatory programs. In January 2006, EPA is planning to release an agency-wide nanotechnology framework that will describe both the potential regulatory issues facing the agency and the research needed to support decisions on those issues.

NIOSH sponsors 8 percent ($3 million) of research on environmental and safety implications of nanotechnology, and its activities are driven by the fact that minimal information is currently available on dominant exposure routes, potential exposure levels and material toxicity. NIOSH is attempting fill those gaps by building on its established research programs on ultra-fine particles (typically defined as particles smaller than 100 nanometers). The National Toxicology Program, an interagency collaboration between NIOSH and NIEHS, also supports a portfolio of projects studying the toxicity of several common nanomaterials, including quantum dots, buckyballs, and the titanium dioxide particles that have been used in cosmetics. NIOSH published a draft research strategy in late September 2005.

Private Sector Research

There is little information about how much individual companies are investing in research on the environmental and safety implications of nanotechnology. There are, however, a variety of activities underway in industry associations emphasizing the importance of research in this area. Members of the American Chemistry Council's ChemStar panel, for example, have committed to ensuring that the commercialization of nanomaterials proceeds in ways that protect workers, the public and the environment. Other elements of the chemical and semiconductor industries have formed the Consultive Boards for Advancing Nanotechnology, which has developed a list of key research and evaluation, identifying toxicity testing, measurement, and worker protection.

Potential Regulatory and Policy Issues.

Some companies, especially large firms that operate in many industry sectors, have significant experience dealing with environmental issues and risk management plans, are comfortable dealing with potential environmental and safety implications arising from nanotechnology. However, many companies that are involved with nanotechnology-related products are small, start-up companies or small laboratories with less experience in this area. According to the Lux Research report described above, some of these small enterprises do not carry out testing because

[12] "Nanotechnology Grand Challenge in the Environment: Research Planning Workshop Report," from the workshop held May 8-9, 2003, is available online at http://es.epa.gov/ncer/publications/nano/nanotechnology4-20-04.pdf.

they lack the resources to do so, while others do not do so because of fear they might learn something that could create legal liability or create barriers to commercializing their product.

At EPA, the regulatory program offices are trying to determine whether and to what degree existing regulatory programs can and should be applied to nanotechnology. For example, EPA is considering how the Toxic Substances Control Act (TSCA) will apply to nanotechnology, having recently approved the first nanotechnology under that statute. (See Appendix A for a recent Washington Post article discussing the issue). Enacted in 1976, TSCA authorizes EPA to regulate new and existing chemicals and provides EPA with an array of tools to require companies to test chemicals and adopt other safeguards. Decisions on conventional chemicals under TSCA are driven by a chemical's name, test data, and models of toxicity and exposure. Because much of this information does not yet exist for nanotechnology, EPA is having a difficult time deciding how best to proceed. The lack of information led to EPA's recent proposal to create a voluntary program under which companies would submit information that would help the agency learn about nanotechnology more quickly. EPA is now evaluating all of its water, air and land regulatory responsibilities to determine whether and how EPA should handle nanotechnology in these areas.

Other federal agencies with regulatory responsibilities, such as the Food and Drug Administration and the Occupational Safety and Heath Administration, are also trying to determine how they will address environmental and safety concerns related to nanotechnology.

A number of observers, including the United Kingdom's Royal Society,[13] have suggested a precautionary approach to nanotechnology until more research has been completed. They urge caution especially regarding applications in which nanoparticles will be purposely released into environment. Examples of these so-called dispersive uses are nanomaterials used to clean contaminated groundwater or those that when discarded enter the sewer system and thereby the nation's waterways.

9. Witness Questions

The witnesses were asked to address the following questions in their testimony:

Questions for Dr. Clayton Teague

In your testimony, please briefly describe current federal efforts to address possible environmental and safety risks associated with nanotechnology and address the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

[13] The United Kingdom's Royal Society and Royal Academy of Engineering's report "Nanoscience and Nanotechnologies: Opportunities and Uncertainties" was published in July 2004 and is available online at http://www.nanotec.org.uk/finalReport.htm

- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- How much is the federal government spending for research on environmental and safety implications of nanotechnology? Which agencies have the lead? What additional steps are needed?

Questions for Mr. Matthew Nordan

In your testimony, please briefly describe the major findings of the Lux Research report on environmental and safety issues associated with nanotechnology and address the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Dr. Krishna Doraiswamy

In your testimony, please briefly describe what DuPont is doing to address possible environmental and safety risks associated with nanotechnology and answer the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Mr. David Rejeski

In your testimony, please briefly describe the major findings of the Wilson Center's recent study on public perceptions about nanotechnology and answer the following four questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Dr. Richard Denison

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Appendix A: Washington Post Article on Nanotechnology and Safety

Nanotechnology's Big Question: Safety
Some Say Micromaterials Are Coming to Market Without Adequate Controls
The Washington Post
October 23, 2005, page A11
By Juliet Eilperin, Washington Post Staff Writer

With little fanfare, the Environmental Protection Agency has for the first time ruled on a manufacturer's application to make a product composed of nanomaterials, the new and invisibly small particles that could transform the nation's engineering, industrial and medical sectors.

The agency's decision to approve the company's plan comes amid an ongoing debate among government officials, industry representatives, academics and environmental advocates over how best to screen the potentially toxic materials. Just last week, a group of academics, industry scientists and federal researchers, working under the auspices of the nonprofit International Life Sciences Institute, outlined a set of principles for determining the human health effects of nanomaterial exposures.

By year-end, the EPA plans to release a proposal on how companies should report nanomaterial toxicity data to the government.

"Toxicity studies are meaningless unless you know what you're working with," said Andrew Maynard, who helped write the institute's report and serves as chief science adviser to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, a Washington-based think tank.

Because of their tiny size, nanomaterials have special properties that make them ideal for a range of commercial and medical uses, but researchers are still trying to determine how they might affect humans and animals. Gold, for example, may behave differently when introduced at nanoscale into the human body, where it is chemically inert in traditional applications.

The institute's report urged manufacturers and regulators to evaluate the properties of nanomaterials in laboratory tests, adding: "There is a strong likelihood that the biological activity of nanoparticles will depend on physiochemical parameters not routinely considered in toxicology studies."

The EPA decided last month to approve the "pre-manufacture" of carbon nanotubes, which are hollow tubes made of carbon atoms and potentially can be used in flat-screen televisions, clear coatings and fuel cells. The tubes, like other nanomaterials, are only a few ten-thousandths the diameter of a human hair.

Jim Willis, who directs the EPA's chemical control division in the Office of Pollution Prevention and Toxics, said he could not reveal the name of the company that received approval for the new technology or describe how that technology might be marketed. He added, however, that the EPA reserved the right to review the product again if the company ultimately decides to bring it to market.

Nanomaterials are already on the market in cosmetics, clothing and other products, but these items do not fall under the EPA's regulatory domain. EPA officials judge applications subject to the Toxic Substances Control Act (TOSCA), a law dating from the mid-1970s that applies to chemicals.

In a Wilson Center symposium last Thursday, Willis said "it is a challenge" to judge nanotechnology under existing federal rules.

"Clearly, [TOSCA] was not designed explicitly for nanoscale materials," he said, but he added that chemicals "have quite a number of parallels for nanoscale materials" and that "in the short term, we are going to learn by doing."

Scientific studies also suggest nanoparticles can cause health problems and damage aquatic life. For instance, they lodge in the lungs and respiratory tract and cause inflammation, possibly at an even greater rate than asbestos and soot do.

“Nanoparticles are like the roach motel. The nanoparticles check in but they don’t check out,” said John Balbus, health program director for the advocacy group Environmental Defense. “Part of this is a societal balancing act. Are these things going to provide such incredible benefits that we’re willing to take some of these risks?”

Nanomaterials have possible environmental advantages as well. For instance, they can absorb pollutants in water and break down some harmful chemicals much more quickly than other methods.

“Just because something’s nano doesn’t mean it’s necessarily dangerous,” said Kevin Ausman, executive director of Rice University’s Center for Biological and Environmental Nanotechnology. He added that when it comes to nanotechnology’s toxic effects, “we’re trying to get that data before there’s a known problem, and not after there’s a known problem.”

Companies such as DuPont are pushing to establish nanotechnology safety standards as well, in part because they have seen how uncertainties surrounding innovations—such as genetically modified foods—have sparked a backlash among some consumers.

“The time is right for this kind of collaboration,” said Terry Medley, DuPont’s global director of corporate regulatory affairs. “There’s a general interest on everyone’s part to come together to decide what’s appropriate for this technology.”